

WE CLAIM:

1. In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and

(3) means for securely attaching said prosthesis body to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and

B) a tool for attaching said flexible sewing cuff to the patient in a minimally invasive manner and which includes

(1) a housing,

(2) an operating handle mounted on one end of said housing,

(3) at least one fastener stored in said housing, said fastener having an elastic limit,

(4) means for releasably mounting said flexible sewing cuff to said tool, and

(5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

2. The tool defined in Claim 1 further including means for separating the tool from the prosthesis.

3. In combination:

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- A) a multipart prosthesis which includes
- (1) a flexible sewing cuff,
 - (2) a prosthesis valve separate from said flexible sewing cuff, and
 - (3) means for attaching said prosthesis body to said flexible sewing cuff after said flexible sewing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
- (1) a housing,
 - (2) an operating handle mounted on said housing,
 - (3) at least one fastener stored in said housing, said fastener having an elastic limit,
 - (4) means for releasably mounting said flexible sewing cuff to said tool, and
 - (5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.
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4. The tool defined in Claim 3 wherein each fastener includes a tissue-penetrating portion and anchoring means on said tissue-penetrating portion for anchoring said tissue-penetrating after the tissue-penetrating portion has passed through the patient's tissue.

Combination
5. The ~~tool~~ defined in Claim 4 wherein the tissue-penetrating portion includes two legs and the anchoring means includes a spring base which is biased to force the legs of the tissue-penetrating portion into a position in which the legs overlap each other.

Combination
6. The ~~tool~~ defined in Claim 3 wherein the fastener ^{of the tool} includes a helical portion.

Combination
7. The ~~tool~~ defined in Claim 3 wherein each fastener ^{of the tool} includes a tissue-penetrating portion which includes anti-backup barbs.

combination
8. The ~~tool~~ defined in Claim 3 wherein said fastener handling means ^{of the tool} includes means for storing fasteners and means for opening fasteners.

combination
9. The ~~tool~~ defined in Claim 3 wherein said fastener handling means ^{of the tool} includes means for storing fasteners and means for imparting rotation to said fasteners.

Combination
10. The ~~tool~~ defined in Claim 3 wherein said fastener handling

^{of the tool}
means includes means for storing fasteners and means for
advancing fasteners one at a time.

11. The ^{Combination} tool defined in Claim 1 further including means for operating said operating handle which includes a housing; a handle pivotally mounted on said handle; means for translating pivoting movement of said handle into rotational motion; and means for connecting the translating means to a fastener.

12. In combination:

A) a heart valve prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve body separate from said flexible sewing cuff, and

(3) means for securely attaching said valve body to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and

B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes

(1) a housing,

(2) an operating handle mounted on said housing,

(3) at least one fastener stored in said housing, said fastener having an elastic limit,

(4) means for releasably mounting said flexible sewing cuff to said tool, and

(5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled

by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

13. In combination:

- A) a multipart heart valve prosthesis which includes
- (1) a flexible sewing cuff,
 - (2) a prosthesis heart valve body separate from said flexible sewing cuff,
 - (3) means for attaching said heart valve body to said flexible sewing cuff after said flexible sewing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
- (1) a housing,
 - (2) an operating handle mounted on said housing,
 - (3) at least one fastener stored in said housing, said fastener having an elastic limit,
 - (4) means for releasably mounting said flexible sewing cuff to said tool, and
 - (5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming

said fastener beyond its elastic limit.

14. In combination:

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- A) a heart valve prosthesis which includes
- (1) a flexible sewing cuff,
 - (2) a prosthesis valve separate from said flexible sewing cuff, and
 - (3) means for securely attaching said valve body to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
- (1) a housing,
 - (2) an operating handle mounted on said housing,
 - (3) at least one fastener stored in said housing, said fastener having an elastic limit, and
 - (4) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

15. In combination:

- A) a heart valve prosthesis which includes
- (1) a flexible sewing cuff,
- 96

(2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and

(3) means for securely attaching said valve body to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and

B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes

(1) a housing,

(2) an operating handle mounted on said housing,

(3) at least one fastener stored in said housing, said fastener having an elastic limit, and

(4) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

16. In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and

(3) said prosthesis valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and

B) a tool for attaching said flexible sewing cuff to the

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from one side of said sewing cuff, said fastener having an elastic limit; and

C) means for forcing said fastener through said sewing cuff and attaching said sewing cuff to the patient without exceeding the elastic limit of said fastener whereby said fastener is non-formed when said sewing cuff is attached to the patient by said fastener.

20. In combination:

A) a multipart heart valve prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis heart valve separate and spaceable from said flexible sewing cuff, and

(3) said prosthesis heart valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient;

B) a fastener for attaching said sewing cuff to the patient from one side of said sewing cuff, said fastener having an elastic limit and an initial shape; and

C) means for forcing said fastener through said sewing cuff and attaching said sewing cuff to the patient without exceeding the elastic limit of said fastener whereby said fastener is non-formed and not permanently deformed from the initial shape when said flexible sewing cuff is attached to the patient by said fastener.

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